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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

HOWARD, ZACHARY C

ART UNIT

PAPER NUMBER

1646

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/533,843 | <b>Applicant(s)</b><br>HAGEN, FREDERICK S. |  |
|                              | <b>Examiner</b><br>Zachary C. Howard | <b>Art Unit</b><br>1646                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Status of Application, Amendments and/or Claims***

Claims 1-54 are pending in the instant application.

### ***Species Elections***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Five separate elections of species are required as follows:

(1) Applicant is required to elect a single species of processed membrane protein from the group consisting of: Angiotensin converting enzyme (ACE);  $\beta$ -amyloid precursor protein (APP); other  $\beta$ -amyloids; transforming growth factor- $\alpha$  (TGF- $\alpha$ ); tumor-necrosis factor- $\alpha$  (TNF- $\alpha$ ); tumor necrosis factor receptor I (TNFR-I); tumor necrosis factor receptor II (TNFR-II); Fas Ligand (FasL), Interleukin-6 receptor (IL6R), or other processed membrane protein. It is noted that each of these species is disclosed on page 1 of the specification.

The claims are deemed to correspond to these species in the following manner:

Claims 1-46 are generic with respect to the species of processed membrane protein.

Claims 47-54 are directed to the species of angiotensin converting enzyme (ACE).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each species of processed membrane protein is a structurally discrete molecule made of a different sequence of amino acids. Lack of unity is shown because these proteins lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(2) Applicant is required to elect a single species of disease associated with the release fragment of the processed protein from the group consisting of: inflammatory disease, cancer, diabetes, Alzheimer's disease, or Parkinson's disease.

The claims are deemed to correspond to these species in the following manner:

Claim 5 is generic with respect to the species of associated disease.

Claim 6 recites each species as a Markush-type group.

Claims 1-4 and 8-54 do not specifically recite a genus of associated disease, but are methods using comprising-type language, and therefore broadly encompass any type of associated disease.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each species of associated disease has a different etiology, affected tissue, and mode of treatment. Lack of unity is shown because these diseases lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(3) Applicant is required to elect a single species of agent from the group consisting of: small molecule or peptide.

The claims are deemed to correspond to these species in the following manner:

Claims 1-8, 10, 13, 36-46 are generic with respect to the species of agent.

Claims 9 and 12 correspond to the species of small molecule.

Claims 11, 14-35, and 47-54 correspond to the species of peptide.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: small molecules and peptides are structurally discrete molecules. Lack of unity is shown because these proteins lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(4) Applicant is required to elect a single species of presentation molecule from the group consisting of: CD24; IL-3 receptor; and thioredoxin.

The claims are deemed to correspond to these species in the following manner:

Claims 1-29 and 33-54 are generic with respect to the species of presentation molecule.

Claims 30-32 each correspond to one of the species listed above.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each species of presentation molecule is a structurally discrete molecule made of a different sequence of amino acids. Lack of unity is shown because these proteins lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(5) Applicant is required to elect a single species of complex biological fluid from the group consisting of: blood, serum, plasma and cerebral spinal fluid (CSF).

The claims are deemed to correspond to these species in the following manner:

Claims 1-40 and 42-54 are generic with respect to the species of complex biological fluid.

Claim 41 corresponds to each of the species listed above.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each species of complex biological fluid is composition comprising numerous different proteins and other biomolecules. Lack of unity is shown because these proteins lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

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Applicant is required, in reply to this action, to elect a single species of (1) processed membrane protein; (2) disease associated with the release fragment of the processed protein; (3) agent; (4) presentation molecule; and (5) complex biological fluid to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646